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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,693	09/12/2005	Ben Adler	I-2002.011 US	8800
31846 7590 12/04/2007 INTERVET INC. PATENT DEPARTMENT PO BOX 318 MILLSBORO, DE 19966-0318			EXAMINER GANGLER, BRIAN J	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 12/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/521,693

Applicant(s)

ADLER ET AL.

Examiner

Brian J. Gangle

Art Unit

1645

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 30 October 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 24, 29 and 33.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

### ADVISORY ACTION

Applicant's amendment filed 10/30/2007, under 37 DFR 1.116, in reply to the final rejection, has been considered and is hereby entered.

Claims 24, 29, and 33 are amended. Claims 24, 29, and 33 are pending and are currently under examination.

#### *Specification*

The objection to the specification because of improper use of trademarks is maintained. Although applicant has amended the specification to capitalize trademark names, applicant has not included appropriate generic descriptions (specifically for SPAN and TWEEN). It is suggested that applicant consult the MSDS sheets to determine the appropriate generic descriptions.

**Applicant argues:** that, when reviewed in context, it is clear what each of the trademarked products is. Applicant points to page 21, where SPAN and TWEEN are identified as emulsifiers.

Applicant's arguments have been fully considered and deemed non-persuasive.

There are numerous "emulsifiers," including items such as lecithin, nonoxynol, sodium dodecyl sulfate, polysorbate, and many others. Thus, the term "emulsifier" does not provide a suitable description of either SPAN or TWEEN. Both of these products have generic chemical names. It is these names that are required. As stated previously, it is suggested that applicant consult the MSDS sheets to determine the appropriate generic descriptions.

#### *Claim Objections Withdrawn*

The rejection of claim 24 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a diagnostic kit for detecting antibodies directed against a 61 kD *Brachyspira hyodysenteriae* lipoprotein having the amino acid sequence of SEQ ID NO:2, comprising an immunogenic 61 kD *Brachyspira hyodysenteriae* lipoprotein having the amino

acid sequence of SEQ ID NO:2, does not reasonably provide enablement for the claim as recited, is withdrawn in light of applicant's amendment thereto.

***Claim Rejections Maintained***

***35 USC § 102 and 103***

The rejection of claims 24, 29-30, and 33 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Thomas *et al.* (Infect. Immun., 60:3111-3116, 1992; IDS filed 1/18/2005), is maintained for the reasons set forth in the previous office action.

**Applicant argues:**

1. That the prior art does not teach an isolated and purified protein having the sequence of SEQ ID NO:2. Applicant asserts that the art does not teach a particular isolated and purified protein, but only bands on gels, "which are multiple proteins."

2. That "the skilled practitioner was not enabled to determine that there existed a single protein having this sequence and could not have determined that from the publication cited."

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, the prior art clearly teaches proteins run through a gel electrophoresis separation. The art shows a band containing a lipoprotein of the same size as that claimed by applicant. As stated previously, the sequence of a protein is an inherent characteristic that does not render said protein novel. Applicant has presented no evidence whatsoever that there are multiple 61kd lipoproteins found in *Brachyspira hyodysenteriae* or that the protein shown in the art is different from the claimed protein. Applicant continues to assert that electrophoretic bands contain multiple proteins. This is immaterial to the instant case. The bands shown in the art would contain the claimed protein. Gel electrophoresis is a separation procedure listed in many textbooks as a means of isolating or purifying proteins. The proteins found in these gels have been isolated and purified from other cellular components.

Regarding argument 2, separating proteins by gel electrophoresis is practiced even by undergraduate students; thus, the skilled artisan could easily have produced the claimed protein. Whether or not the sequence of the protein was known is not relevant, since the sequence of a

protein is an inherent characteristic that does not render said protein novel. However, if the artisan had chosen to sequence said protein, automated sequencing procedures are widely known. It is also widely known in the art that a band cut from a gel after electrophoresis is used in such automated sequencing procedures.

The rejection of claims 24, 29-30, and 33 under 35 U.S.C. 102(b), as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chatfield *et al.* (Infect. Immun., 56:1070-1075, 1988; IDS filed 1/18/2005), is maintained for the reasons set forth in the previous office action.

**Applicant argues:**

1. That the prior art does not teach an isolated and purified protein having the sequence of SEQ ID NO:2. Applicant asserts that the art does not teach a particular isolated and purified protein, but only bands on gels, "which are multiple proteins."

2. That "the skilled practitioner was not enabled to determine that there existed a single protein having this sequence and could not have determined that from the publication cited."

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, the prior art clearly teaches proteins run through a gel electrophoresis separation. The art shows a band containing a lipoprotein of the same size as that claimed by applicant. As stated previously, the sequence of a protein is an inherent characteristic that does not render said protein novel. Applicant has presented no evidence whatsoever that there are multiple 61kd lipoproteins found in *Brachyspira hyodysenteriae* or that the protein shown in the art is different from the claimed protein. Applicant continues to assert that electrophoretic bands contain multiple proteins. This is immaterial to the instant case. The bands shown in the art would contain the claimed protein. Gel electrophoresis is a separation procedure listed in many textbooks as a means of isolating or purifying proteins. The proteins found in these gels have been isolated and purified from other cellular components.

Regarding argument 2, separating proteins by gel electrophoresis is practiced even by undergraduate students; thus, the skilled artisan could easily have produced the claimed protein. Whether or not the sequence of the protein was known is not relevant, since the sequence of a

protein is an inherent characteristic that does not render said protein novel. However, if the artisan had chosen to sequence said protein, automated sequencing procedures are widely known. It is also widely known in the art that a band cut from a gel after electrophoresis is used in such automated sequencing procedures.

The rejection of claims 24, 29-30, and 33 under 35 U.S.C. 102(b), as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wannemuehler *et al.* (Infect. Immun., 56:3032-3039, 1988; IDS filed 1/18/2005), is maintained for the reasons set forth in the previous office action.

**Applicant argues:**

1. That the prior art does not teach an isolated and purified protein having the sequence of SEQ ID NO:2. Applicant asserts that the art does not teach a particular isolated and purified protein, but only bands on gels, "which are multiple proteins."

2. That "the skilled practitioner was not enabled to determine that there existed a single protein having this sequence and could not have determined that from the publication cited."

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, the prior art clearly teaches proteins run through a gel electrophoresis separation. The art shows a band containing a lipoprotein of the same size as that claimed by applicant. As stated previously, the sequence of a protein is an inherent characteristic that does not render said protein novel. Applicant has presented no evidence whatsoever that there are multiple 61kd lipoproteins found in *Brachyspira hyodysenteriae* or that the protein shown in the art is different from the claimed protein. Applicant continues to assert that electrophoretic bands contain multiple proteins. This is immaterial to the instant case. The bands shown in the art would contain the claimed protein. Gel electrophoresis is a separation procedure listed in many textbooks as a means of isolating or purifying proteins. The proteins found in these gels have been isolated and purified from other cellular components.

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protein is an inherent characteristic that does not render said protein novel. However, if the artisan had chosen to sequence said protein, automated sequencing procedures are widely known. It is also widely known in the art that a band cut from a gel after electrophoresis is used in such automated sequencing procedures.

### *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PRIMARY EXAMINER